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PATENT
Attorney Docket No. 017622-000130US

TOWNSEND and TOWNSEND and CREW LLP

By: Jeannette Yandolo

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: application of:

TONY REID

Application No.: 10/725,837

Filed: December 1, 2003

For: MULTIPLE SLEEVE METHOD
AND APPARATUS FOR TREATING
EDEMA AND OTHER SWELLING
DISORDERS

Confirmation No. 3216

Examiner: Clinton T. OSTRUP

Technology Center/Art Unit: 3771

APPELLANTS' REPLY BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Answer mailed September 2, 2008 for the above-referenced application, Appellants submit this Reply Brief under 37 C.F.R. 41.41.

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1. REAL PARTY IN INTEREST

The real party in interest of the present patent application is the inventor and owner, Tony Reid.

2. RELATED APPEALS AND INTERFERENCES

In a previous appeal regarding this application, the Board of Patent Appeals and Interferences affirmed the obviousness rejection of claims that were substantively different from those currently pending. *See Ex parte Reid* Decision ("Decision") mailed January 8, 2007 at 1.

3. STATUS OF CLAIMS

Claims 1-10 stand finally rejected and are the subject of this appeal.

4. STATUS OF AMENDMENTS

Claim amendments filed August 23, 2007 have been entered.

A claim amendment to correct typographical errors in claim 5 was submitted in the Appeal Brief filed March 26, 2008. The amendment was refused in an Advisory Action mailed June 2, 2008. The Advisory Action incorrectly stated that the proposed amendment "creates new issues including a lack of antecedent basis for 'the first sleeve' as claimed in dependent claim 10." However, Appellants respectfully point out that claim 10 depends from claim 1, not claim 5.

Because Appellants are unable to correct claim 5 at this time, Appellants submit this Amended Appeal Brief presenting the unamended claim 5 as requested by the Advisory Action. Appellants respectfully request that the Patent Office afford the opportunity to amend claim 5 as proposed (e.g., via an Examiner's Amendment after the Appeal has been decided).

5. SUMMARY OF CLAIMED SUBJECT MATTER

Embodiments of the invention provide systems, methods, and apparatus to relieve swelling in limbs. Embodiments of the invention are particularly useful for applying variegated pressure along the full length of a patient's limb to reduce swelling due to lymphedema, edema,

and other swelling disorders such as venous insufficiency. *See* the published specification at, *inter alia*, paragraphs [0032] and [0057].

Independent claim 1 is directed to a system for applying pressure to a body limb, the system comprising a first sleeve and a second sleeve. The first sleeve has a foam lining and is configured to be slid (i.e., it is capable of sliding) over the full length of the limb. The second sleeve is the same length as the first sleeve and is configured to be slid (i.e., it is capable of sliding) over the full length of the first sleeve to apply additional inward pressure along the length of the limb.

Independent claim 5 is directed to a system for applying pressure to an arm, the system comprising an inner therapeutic pressure sleeve and at least one second sleeve. The therapeutic pressure sleeve has a ridged inner surface and slides over the entire length of the arm from the shoulder to the wrist. The second sleeve is the same length as the therapeutic pressure sleeve and slides over the entire length of the therapeutic pressure sleeve to apply additional inward pressure on the arm.

Support for claims 1 and 5 can be found in the published specification at, *inter alia*, paragraphs [0052]-[0053], [0057]-[0059], and Fig. 2A.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as obvious in view of U.S. Patent 814,795 ("Myers") and U.S. Patent 5,171,211 ("Deasy"). Appellants appeal the rejection of these claims collectively, as described in detail below.

7. ARGUMENT

A. Obviousness (Reiterated from Replacement Brief filed July 1, 2008)

1. Applicable Law of Obviousness

To establish *prima facie* obviousness, the prior art references, when combined, (1) must teach or suggest all the claim limitations; (2) there must be some suggestion or motivation to combine the reference teachings; and (3) there must be a reasonable expectation of success. M.P.E.P. § 2143.

Regarding the motivation to combine, although there must be some teaching in the prior art that would motivate a person of ordinary skill to combine the references, the teaching need not be expressly stated in one or all of the cited references. *See KSR Int'l v. Teleflex, Inc.*, 550 U.S. ___, 14-15 (2007). However, in combining or modifying the cited references, the combination or modification cannot render the disclosed device inoperable: "[I]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. § 2143.01.

2. Independent claims 1 and 5 are not obvious in view of Myers and Deasy.

The Final Office Action asserted that claims 1-10 are obvious in view of Myers and Deasy. The Final Office Action stated that Myers discloses a first sleeve having a foam lining with ridges and a second sleeve to be slid over the first sleeve to apply additional inward pressure. Final Office Action dated October 30, 2007 at 2. The Final Office Action recognized, however, that Myers does not teach or suggest a second sleeve having the same length as the first sleeve as presently claimed. *Id.* For this limitation, the Final Office Action relied on Deasy Fig. 7, which according to the Patent Office, depicts "a second sleeve 46 configured to be slid over substantially the entire length of the first sleeve." *Id.* at 2-3; *see also* Decision at 6-7. The Final Office Action concluded that "since Deasy already teaches that the second sleeve is configured to be slid over most of the length of the first sleeve (best seen in fig. 7), therefore it would have been an obvious matter of design choice to modify the size of the second sleeve of Myers to be the same length as the first sleeve." Final Office Action dated October 30, 2007 at 3. Appellants disagree.

In the present application, each of independent claims 1 and 5 requires a second sleeve having the same length as the first sleeve or therapeutic pressure sleeve. None of the cited references, even when combined, teach or suggest this limitation.

Myers discloses an elastic bandage having "a series of outer encircling bands, which may be either be integral or separately applied in order to give greater compression than

the bandage alone at any desired point." Col. 1, lines 42-46, Fig. 1. However, each outer encircling band is depicted as applying pressure to only a narrow point on the limb, rather than along the entire length of the bandage. Accordingly, the Final Office Action acknowledged that Myers does not teach or suggest a second sleeve having the same length as the first sleeve. Final Office Action dated October 30, 2007 at 2.

The Patent Office improperly relied on Deasy to overcome the deficiency of Myers. However, Deasy does not teach or suggest a second sleeve having the same length as the first sleeve. Deasy discloses an elastic garment that includes a coat-like portion 16 and tubular arm portions 18 depicted in Fig. 5. The coat-like portion "includes a pair of integral sleeves 46 which are adapted to extend beyond or below the elbow joints 48 of a user." Col. 4, lines 11-15. The tubular arm portions have a length "such as to extend from the wrist of a user up beyond the elbow joint 48 so as to form an overlap with the sleeves 46 of the coat-like portion." Col. 4, lines 30-34. Fig. 7 depicts the overlapping integral sleeve and tubular arm portion. As shown, the Deasy garment covers the user's arm in three sections: (1) from the shoulder toward the elbow, the arm is covered only by the integral sleeve, (2) over the elbow joint, the arm is covered by both the integral sleeve and the tubular arm portion, and (3) from the wrist toward the elbow, the arm is covered only by the tubular arm portion. The integral sleeves and tubular arm portions also feature enlarged beads along the edges that "in effect act like a garter in compressing the body part of the user immediately beneath the bead." Col. 4, lines 49-53. Fig. 7 shows the enlarged beads above and below the elbow joint.

Nothing in Deasy teaches or suggests that the tubular arm portion may extend from the wrist all the way up to the shoulder. Similarly, nothing in Deasy teaches or suggests that the integral sleeve may extend from the shoulder all the way down to the wrist. To the contrary, the sole independent claim recites that "the component parts are adapted to overlap only at said joint" of a user's body. Claim 1 (emphasis added). The garment is claimed as having one component positioned "immediately above and across a joint," and another component positioned "immediately below and across said joint." Claim 1 (emphasis added). Because Deasy explicitly teaches a second sleeve that only partially overlaps the first sleeve,

Deasy cannot be relied upon for teaching a second sleeve that overlaps the entire length of the first sleeve as presently claimed.

Moreover, if Deasy were modified by extending the sleeves to completely overlap, the modification would render Deasy unsatisfactory for its intended purposes. Deasy discloses that a significant advantage of the garment is the ability "to be easily put on." Col. 2, line 17. If Deasy were modified by extending the sleeves to completely overlap, the garment would be increasingly difficult to take on and take off because of the increased friction between the sleeves. Deasy also discloses that the garment provides beneficial circulatory effects due to the enlarged beads formed from the edges of the garment components. The beads create "a garter effect at locations above and below the knee joints and the elbow joints [which] provides anatomical reactions which improve the therapeutic and other benefits of the garment." Col. 5, lines 1-9. If Deasy were modified by extending the sleeves to completely overlap along the length of the arm, the enlarged beads formed from the edges of the components would be positioned at the wrist and shoulder, rather than above and below the elbow joint. Any circulatory benefits of the Deasy garment might be lost by the modification. Because an obviousness rejection cannot be based on a modification that would render the disclosed apparatus unsatisfactory for its intended purpose, the outstanding obviousness rejection in this case cannot rely on modifying Deasy by extending the sleeves to completely overlap. *See In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). Such a modification would render the Deasy garment unsatisfactory for both stated purposes.

Thus, contrary to the Final Office Action, Deasy does not teach or suggest a second sleeve configured to be slid over the entire length of the first sleeve. One of ordinary skill in the art would not have modified Deasy in a way that (1) directly contradicts its disclosure that the sleeves should overlap only at the joint, and (2) renders the Deasy garment unsatisfactory for its intended purposes. Because the cited references, even in combination, do not teach or suggest every limitation of the claims, the Patent Office has not set forth a *prima facie* case of obviousness. Appellants respectfully request reconsideration and withdrawal of the rejection.

3. Dependent claims 2-4 and 6-10 are likewise not obvious.

Each of the dependent claims 2-4 and 6-10 include the limitations of the independent claims. Thus, because Myers and Deasy fail to teach or suggest every limitation of the independent claims, the cited references likewise fail to teach or suggest every limitation of the dependent claims. For at least the reasons detailed above, Myers and Deasy fail to render obvious dependent claims 2-4 and 6-10.

4. Criticality

The Final Office Action asserted that the specification describes alternative embodiments that are not encompassed by the pending claims. Final Office Action dated October 20, 2007 at 3-4. In particular, Fig. 6 depicts an embodiment having a second sleeve shorter than the first sleeve. *See also* published specification at paragraph [0063]. The Final Office Action asserted:

Therefore, absent a teaching as to criticality that the second sleeve being configured to be slid *wholly* over the entire length of the first sleeve, this particular arrangement is deemed to have been known by those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement. Final Office Action dated October 20, 2007 at 4 (emphasis in original).

Appellants disagree that a showing of criticality is required. Appellants are entitled to present claims directed to one or more particular embodiments. *See, e.g.,* M.P.E.P. § 806.04(e) ("The scope of a claim may be limited to a single disclosed embodiment."). Particularly in this instance, where other related patents may claim alternative embodiments, Appellants are not required to draft claims that encompass the entire teaching of the specification. In fact, the specification of any patent application is likely to disclose both subject matter known in the prior art as well as novel subject matter. *See, e.g.,* M.P.E.P. § 608.01(c)(2) (The specification may include a background "paragraph(s) describing to the extent practical the state of the prior art."). That the specification may describe an unclaimed feature that was known in the prior art does not destroy the patentability of the pending claims directed to a novel embodiment.

5. The Board's previous Decision considered substantively different claims.

In a previous appeal regarding this application, the Board of Patent Appeals and Interferences ("Board") affirmed the obviousness rejection of claims that were substantively different from those currently pending. *See* Decision mailed January 8, 2007. The previously pending claims recited, in part, "a second sleeve configured to be slid over substantially the entire length of the first sleeve." *See* Appendix A of Appeal Brief filed August 26, 2005 (emphasis added).

The Board found that "substantially" means "largely" or "approximately" rather than "perfectly." Decision at 5. The Board stated: "There is nothing in the specification of the present application that clearly and unmistakably limits claim 1 or claim 5 to the embodiment illustrated in Figs. 1, 2A and 2B." *Id.* The Board held that because Fig. 7 of Deasy illustrated a sleeve that "overlaps significantly more than half of the length of the arm portion 18 in a region extending from well above the elbow to well below the elbow of the user," Deasy satisfied the limitation of "configured to be slid over substantially the entire length of the first sleeve [TPS]." *Id.* at 6-7.

Because the claims now facing the Board are substantively different from those previously presented to the Board, the previous Decision does not direct the outcome of the present appeal. Notably, the previous claims recited a substantial overlap, whereas the currently pending claims recite a second sleeve "configured to be slid wholly over the entire length of the first sleeve." If any instruction is to be gleaned from the previous Decision, it is that the outcome might have been different if claims 1 or 5 were limited to the embodiments illustrated in Figs. 1, 2A, and 2B. *See* Decision at 5. The claims have been amended to include precisely such a limitation. The claims are now directed to a second sleeve wholly overlapping the entire length of the first sleeve. The cited references disclose a second sleeve that only substantially overlaps the first sleeve. As the Board recognized, "wholly" and "substantially" are not identical in meaning. *Id.* Thus, even if the cited references teach or suggest substantially overlapping sleeves, such a holding does not mean that the cited reference teach or suggest wholly

overlapping sleeves. As described in detail above, the cited references do not in fact teach this limitation.

B. Response to Examiner's Amendment mailed September 2, 2008

The Examiner acknowledges that a *prima facie* case of obviousness requires that the references, when combined, must teach or suggest all the claim limitations. But the Examiner fails to recognize that the cited references, even when combined, do not teach or suggest a first and second sleeve that are both configured to be slid over the entire length of the limb. (The first sleeve is configured to be slid over the entire length of the limb, and the second sleeve is configured to be slid over the entire length of the first sleeve. Thus, both sleeves are configured to be slid over the full length of the limb.)

The Examiner asserts that it would have been obvious to "modify the size of the elastic bandage *and* corresponding outer sleeve to fit the portion of the body requiring treatment." Examiner's Answer at 8 (emphasis added). Thus, the Examiner recognizes that the claimed invention differs from the prior art with respect to the size of the elastic bandage (e.g., first sleeve), the size of the corresponding outer sleeve (e.g., the second sleeve), as well as the degree of overlap between the two. The Examiner's suggested combination of references and modifications thereto require one of ordinary skill in the art to change all three of these variables. Moreover, one of ordinary skill in the art must have been motivated to make these modifications **in direct contradiction to both references.**

Myers teaches applying "localized compression, as of a tourniquet" to "any desired point." Myers col. 2, lines 63-64 and col. 1, lines 14 and 46. Deasy expressly teaches that the sleeves "are adapted to overlap **only at said joint.**" Deasy claim 1 (emphasis added). Thus, both Myers and Deasy **teach away** from modifying the prior art to create two entirely overlapping sleeves, as presently claimed.

In order to arrive at Applicants' invention from the combined references, one would have to make at least the following changes:

1) One would have to select an embodiment of the Myers first sleeve that is configured to be slid over the entire limb as opposed to a merely a portion thereof. For example,

one would have to extend the Myers sleeve depicted in Fig. 1, which shows a sleeve covering only a forearm. *See* Myers Fig. 1 and col. 1, line 23.

2) **In direct contradiction to Myers**, which teaches "localized compression, as of a tourniquet" to "any desired point," one would have to combine the extended first sleeve from step 1 with a second sleeve that applies pressure over the entire length of the limb.

3) **In direct contradiction to Deasy**, which states that the sleeves "are adapted to overlap only at said joint," one would have to modify the second sleeve of Deasy to overlap the entirety of the first sleeve.

In other words, the difference between the prior art and the claimed invention is not merely a difference in size. The claimed invention differs from the cited references, even when combined, in both structure (by changing the length of the second sleeve as well as the degree of overlap between the first and second sleeves) and function (by applying pressure over the entire length of the limb as opposed to localized pressure as taught by both Myers and Deasy). Respectfully, the suggested selections, combinations, and modifications necessary to leap from the prior art to the claimed invention is made only with the benefit of hindsight reconstruction from the Applicants' own disclosure.

The Examiner's Answer relies in part on Deasy's teaching that "[i]t is also possible to only use selected parts of the garment where necessary." *See* Examiner's Answer at 8 and 10 citing Deasy col. 5, lines 19-20. This aspect of the Deasy disclosure is completely irrelevant to the instant discussion. This disclosure merely states that the garment can be used for, e.g., a single limb, as opposed to whole body compression. *See* Deasy col. 5, lines 20-23. This disclosure teaches nothing about modifying the size of the second sleeve or the degree of overlap between sleeves.

Lastly, the Examiner acknowledges that criticality is not required, yet maintains that the second sleeve configured to be slid over the entire length of the first sleeve is "an obvious, non-critical variation of the teachings of the combined references." Deasy teaches that improved therapeutic results are achieved by "the garter effect at locations above and below both the knee joints and the elbow joints." Col. 5, lines 16-19. The Applicants have discovered that a new and different configuration offers advantageous therapeutic benefits: "The device illustrated

in FIGS. 2A and 2B has been successfully employed in a number of test cases." US 2004/0111047 [0065]. It is this successful new configuration that the Applicants now claim.

The claimed invention as depicted in Fig. 2A may now seem apparent with the aid of the Applicants' disclosure, but at the time of the invention, the prior art did not teach or suggest using two sleeves that were both configured to be slid over the entire length of the limb. In fact, the prior art of record **taught away** from whole limb compression. Accordingly, Applicants' respectfully submit that the claimed invention is new and non-obvious.

8. CONCLUSION

For these reasons, it is respectfully submitted that the rejection should be reversed.

The Commissioner is hereby authorized to charge any additional fees associated with this paper, or credit any overpayment, to Deposit Account No. 20-1430.

Respectfully submitted,



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Date: November 3, 2008

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9. CLAIMS APPENDIX

1. (Previously presented) A system for applying pressure to a body limb, said system comprising:

a first sleeve comprising a cylindrical body open at both ends, having a foam lining, and being configured to be slid over the full length of the limb and to apply an inward pressure onto the limb; and

a second sleeve comprising a cylindrical body open at both ends and being configured to be slid wholly over the entire length of the first sleeve such that the second sleeve will have the same length as the first sleeve and will apply additional inward pressure along the full length of the limb when the second sleeve is in place over the first sleeve.

2. (Original) A system as in claim 1, wherein at least the first sleeve has an outer surface with a low coefficient of friction.

3. (Previously presented) A system as in claim 2, wherein at least the second sleeve consists essentially of thin fabric sleeves.

4. (Previously presented) A system as in claim 3, wherein each of the sleeves independently provides an inward pressure in the range from 5 mmHg to 30 mmHg.

5. (Previously presented) A system for applying pressure to an arm, said system comprising:

an innermost therapeutic pressure sleeve (TPS) comprising a cylindrical body open at both ends having ridges formed over an inner surface and configured to be slid over the entire length of the arm from the shoulder to the wrist and to apply an inward pressure thereon; and

at least a second sleeve comprising a cylindrical body open at both ends being configured to be slid wholly over the entire length of the TPS such that the second sleeve will

have the same length as the first sleeve and will apply additional inward pressure onto the limb when the second sleeve is in place over the first sleeve.

6. (Previously presented) A system as in claim 5, wherein the TPS has an outer surface with a low coefficient of friction.

7. (Original) A system as in claim 6, further comprising at least a third sleeve configured to be slid over the second sleeve to apply additional inward pressure onto the limb.

8. (Previously presented) A system as in claim 7, wherein the second and third sleeves consist essentially of thin fabric sleeves.

9. (Previously presented) A system as in claim 8, wherein each of the TPS and sleeves independently provide an inward pressure in the range from 5 mmHg to 30 mmHg when placed over the arm.

10. (Previously presented) A system as in claim 1, wherein the first sleeve is configured to cover an arm from the wrist to near the shoulder.

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.